

### **REMARKS**

The Applicants thank the Examiner for the careful consideration of this application. The Office Action dated June 9, 2008 has been received and its contents carefully considered. Claims 1-3, 6, 8, 10-12, 14-15, 17-20, 23, 25-26, 31-33, 35, 37-40, 44-45, and 74-83 are currently pending in this application. Claim 1 has been amended to delete an optional portion of the claim. Claim 11 has been canceled. As a result, claim 36 has been amended to be dependent from claim 44. Claims 22 and 28-29 have been canceled, and rewritten as new claims 80-82, dependent from claim 37. Claim 36 has been canceled, and rewritten as new claim 83, dependent from claim 44. Claims 23, 25, and 26 have been amended to be dependent from claim 1. Claim 23 has also been amended to add punctuation. Claim 28 has been amended to be dependent from claim 37. Claim 40 has been amended to remove redundancies. Claims 76-79 are new. Support for claims 78-79 is found, for example in claims 1 and 37 respectfully. In accordance with M.P.E.P 2173.05(i), support for the negative limitation in claims 76-77 is found throughout the specification, for example, in paragraphs [0023], [0036], and [0040]. Based on the foregoing amendments and the following remarks, Applicants respectfully request that the Examiner reconsider all outstanding rejections and that they be withdrawn.

### **Claim Objections**

On page 2, the Office Action objects to claim 22 as being in improper independent form. In the interest of advancing prosecution, claim 22 has been canceled. The subject matter of claim 22 is presented in new claim 80, dependent from claim 37.

### **Claim Rejection – 35 U.S.C. § 102**

On pages 2-4, the Office Action rejects claims 1-3, 6, 8, 10-12, 14, 15, 17-20, 22, 23, 25, 26, 28, 29, 31-33, 34-50 [sic], 44 and 45 under 35 U.S.C. § 102(b) as allegedly anticipated by Osipow et al. (U.S. 4328319). Applicants respectfully traverse.

First, the claims are not anticipated by the reference. The reference does not teach all the features of the claims. For instance, the reference does not teach a composition having at least one

film-former comprising from about 0.0001% to about 10% of the composition in a manner sufficient to anticipate the claims. According to the M.P.E.P., "[i]n order to anticipate the claims, the claimed subject matter must be disclosed in the reference with "sufficient specificity to constitute an anticipation under the statute." (see M.P.E.P. 2131.03(II)) The M.P.E.P. also describes an example where the ranges simply overlap, as insufficient for anticipation. (see M.P.E.P. 2131.03(II)) The Office Action indicates Example 1, which has a polymer concentration of 10.4% as anticipating the claim. However, Example 1 lacks other features of at least claim 1 (at least one medicament, for example) and 37 (at least one medicament, at least one solubilizer, or at least one permeation enhancer). Even assuming 10.4% falls within the range of "about 10%," this example cannot support an anticipation rejection since it lacks all the features of the claims. For this reason, the Applicants request the rejections under 35 U.S.C. § 102(b) be withdrawn.

Second, the reference does not teach or reasonably disclose a sprayable composition forming a film upon application. Osipow et al. specifically distinguishes between foamed structures and films in column 15, lines 3-9. Osipow et al. describes a process of solubilizing polymers in a propellant. Although the polymers may be "film-forming" polymers, the composition that is described does not form a film on application to a surface. Rather, the solubilized polymers are coated and dissolved in the propellant, and form foamed structures containing open and/or closed cells. (see for example title, abstract, claim 1, or column 10, lines 5-7) The term "film" is used in the present application according to its ordinary meaning in the art, and nothing in the application indicates that films include foamed structures. For example, paragraph [0039] of the specification states, "the composition so prepared is sprayed from the dispenser onto a topical site, at which site it forms a stable, plastic film or patch." To conclude, as the Office Action does, that the foam-forming compositions described in Osipow et al. form "films" is improper and unreasonable. To do so requires defining "films" differently than the ordinary meaning of the word; the way the term is used in the context of the application; the way in which foams are distinguished in the reference; and the meaning to one of ordinary skill in the art. For at least this reason as well, the reference does not anticipate the claims, and Applicants request the rejections under 35 U.S.C. § 102(b) be withdrawn.

Third, the compositions described in Osipow et al. do not inherently form films as asserted. First, on page 7 of the Office Action the examples highlighted (Example 1) do not have all the

limitations of at least claims 1 and 37, as discussed previously. Second, the assertion that 10.4% may be "about 10%," is irrelevant, because the Example having 10.4% polymer forms a foamed structure, not a film. The teachings of Osipow et al. directly contradict the inherency assertion. According to the M.P.E.P., "the fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic." (See M.P.E.P. 2112(IV)) The M.P.E.P. also describes an example where rejections were reversed because "inherency was based on what would result due to optimization of conditions, not what was necessarily present in the prior art. (See M.P.E.P. 2112(IV), emphasis added) Only by modifying the teachings of Osipow et al. may a composition having all the claimed features be constructed. The Office Action improperly modifies the reference by selecting different portions of the specification without any supportable guidance. This modification is improper for an anticipation rejection. For at least this reason, Applicants request the rejections under 35 U.S.C. § 102(b) be withdrawn.

Claims 2-3, 6, 8, 10-12, 14, 15, 17-20, 23, 25, 26, 28, 29, 31-33, 34-36, 38-40, 44 and 45 depend, directly or indirectly from claims 1 or 37. These claims are allowable for at least the same reasons. Applicants request the rejections of all the claims be withdrawn.

#### **Claim Rejection - 35 U.S.C. §103(a)**

On pages 5-6, the Office Action rejects claims 1-3, 6, 8, 10-12, 14, 15, 17-20, 22, 23, 25, 26, 28, 29, 31-33, 34-40, 44, 45, 74, and 75 as allegedly unpatentable under 35 U.S.C. §103(a) based on Osipow et al. (U.S. 4328319) in view of Biedermann et al. (U.S. 5980921). Applicants respectfully traverse.

First, it is unclear whether the Office Action is rejecting claims 1-3, 6, 8, 10-12, 14, 15, 17-20, 22, 23, 25, 26, 28, 29, 31-33, 34-40, 44, 45, 74, and 75 since it includes no discussion of any claims other than 74 and 75. Applicants respond only to claims 74 and 75, and request clarification.

Claims 74 and 75 depend from claims 1 and 37 respectively. The deficiencies of Osipow et al. (U.S. 4328319) with respect to claims 1 and 37 are discussed above. In particular, Osipow et al.

teach only compositions that form foams. Biedermann et al. (U.S. 5980921) does not cure the deficiencies of Osipow et al. (U.S. 4328319) since it provides no reason to modify the foam-forming compositions of Osipow et al. to make the claimed film-forming compositions. Claims 74 and 75 are allowable for at least the same reasons as claims 1 and 37. Applicants respectfully request the rejections be withdrawn.

### Conclusion

All of the stated grounds of rejection have been properly traversed, accommodated, or rendered moot. Applicant therefore respectfully requests that the Examiner reconsider all presently outstanding rejections and that they be withdrawn. Applicant believes that a full and complete reply has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is hereby invited to telephone the undersigned at the number provided.

The Commissioner is authorized to charge any deficiency in any patent application processing fees pursuant to 37 CFR § 1.17, including extension of time fees pursuant to 37 CFR § 1.17(a)-(d), associated with this communication and to credit any excess payment to Deposit Account No. 22-0261.

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Respectfully submitted,

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